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NUTRITIONALS, HFS-450

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July 8, 1996

Regulatory Branch  
Division of Programs and Enforcement Policy  
Office of Special Nutritionals (HFS-456)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C Street, S.W.  
Washington, DC 20204

Attn: Margaret Binzer  
Consumer Safety Officer.

Re: Phyto-EST™: Statements of Nutritional Support

Ladies/Gentlemen:

Pursuant to Section 6 of the Dietary Supplement Health and Education Act of 1994, 21 U.S.C. § 343(r)(6), this is to notify the Food and Drug Administration that our client Cartilage Technologies, Inc. of Elmsford, New York has within the last 30 days begun marketing its Phyto-EST™ brand dietary supplement containing soya isoflavones (daidzein, genistein and glycitein), with the following labeling statements characterizing the mechanism by which such nutrients act to maintain human body structure or function, or describing general well-being from the consumption of these nutrients:

"Soya isoflavones such as genistein are among the most versatile and powerful nutraceuticals known to modern medical science. Soya isoflavones have been shown in modern scientific research to have powerful anti-oxidant activity and antiangiogenic activity, and they are nature's estrogens to avert menopausal symptoms.

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Division of Programs and Enforcement Policy  
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You can enjoy the diverse health giving benefits of soya isoflavones with Phyto-EST™."

Sincerely yours,



Charles J. Raubichek

CJR/jbh  
cc: Cartilage Technologies, Inc.